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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/714,333

11/14/2003

Anastasia Khvorova

DHARMA 0100-US2

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EXAMINER

PITRAK, JENNIFER S

ART UNIT

PAPER NUMBER

1635

MAIL DATE

DELIVERY MODE

08/28/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/714,333	Applicant(s) KHVOROVA ET AL.	
	Examiner JENNIFER PITRAK	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 43-54,57-60,68,70-77,79,81 and 84-87 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 43-54,57-60,68,70-77,79,81 and 84-87 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :03/25/2009, 03/25/2009, 04/09/2009.

DETAILED ACTION

Remarks

Applicant's amendments and arguments filed 05/12/2009 have been entered and considered. Claims 1-42, 55, 56, 61-67, 69, 78, 80, 82, 83, and 88-91 are canceled. Claims 43-54, 57-60, 68, 70-77, 79, 81, and 84-87 are pending and are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/426,137, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The instant claims are to methods for obtaining an

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siRNA molecule comprising strands that are 19-30 nucleotides in length. Support for this length limitation is not present in Application No. 60/426,137. The '137 application supports an siRNA strand length limitation of between 18-29 nucleotides, but not 19-30 nucleotides. See page 15 of '137 specification, page 19 of the 60/502,050 specification, and page 23 of the instant specification.

The instant claims are afforded the priority date of the 60/502,050 application, which is 09/10/2003.

Claim Rejections - 35 USC § 112 ¶ 1 - New

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 43-54, 57-60, 68, 70-77, 79, 81, and 84-87 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The instant claims have been amended to require that positions are defined in reference to the 5' end of the antisense sequence within the duplex region. There is no support in the instant specification for reference to nucleotide positions within the duplex region. Applicant has argued this rejection previously in the 12/03/2007 response to the final office action dated 11/08/2007. Relevant arguments will be addressed herein.

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Response to relevant arguments

Applicant previously argued (page 21 of 12/03/2007 response) that the instant disclosure emphasizes that one may focus on the duplex region and Applicant referred specifically to the Pregrant Publication of the instant specification, paragraphs [0105] (page 14 of the instant specification), [0118] (page 18 of the instant specification), [0114] (page 16 of the instant specification), [0147] (pages 22-23 of the instant specification), and [0266] (page 48 of the instant specification). This is not persuasive. While it is true that these sections of the specification explain what constitutes a duplex and the number of base-pairs within a duplex, these sections of the specification do not indicate that the nucleotide positions (from -11 to 19 as indicated on page 23 of the specification) of either strand of an siRNA are within a duplex or within the duplex region of an siRNA. The positions from -11 to 19 are defined "with respect to the 5' end of the sense strand" (p.22, line 33 to p.23, line 14).

Claim Rejections - 35 USC § 112 ¶ 2 - New

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 43-54, 57-60, 68, 70-77, 79, 81, and 84-87 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are to a method for obtaining an siRNA, wherein the siRNA comprises an antisense sequence that is 19-30 nucleotide bases in length and a sense sequence that is 19-30

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nucleotide bases in length and said antisense sequence and said sense sequence form a duplex region of 19-30 base pairs comprising the following steps:

- a) selecting a target gene,
- b) identifying a set of candidate siRNA sequences,
- c) applying one or more criteria to each candidate siRNA sequence,
- d) selecting a candidate siRNA sequence wherein said candidate siRNA sequence satisfies said one or more criteria, and
- e) synthesizing an siRNA molecule.

The criteria of step (c) include particular nucleotide inclusions or exclusions at specific positions within the 19-30 base-pair duplex region. According to the specification, the positions of the specific nucleotide inclusions or exclusions are defined by their relative position within the sense strand of an siRNA molecule, as explained on pages 22-23 of the instant specification.

The instant claims refer to positions in the antisense strand or nucleotides in the sense strand that are complementary to nucleotides at specific positions in the antisense strand. As such, the claims are not clear as to the specific positions of the indicated nucleotides, such as the claimed "position 1 of the antisense strand" or "position 10 of the antisense strand", for example.

Therefore, the claims do not distinctly define the metes and bounds of the subject matter

Applicant regards as the invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER PITRAK whose telephone number is (571)270-3061.

The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM, EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Pitrak
Examiner
Art Unit 1635

/Sean R McGarry/
Primary Examiner, Art Unit 1635